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December 17, 2001

FILE: UROC:018USD2





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Commissioner for Patents Washington, DC 20231

RE:

SN 09/974,546 "BIOMARKERS AND TARGETS FOR DIAGNOSIS, PROGNOSIS AND MANAGEMENT OF PROSTATE, BREAST AND BLADDER CANCER" — Gang An. et al.

Sir:

Enclosed for filing in the above-referenced patent application is an Information Disclosure Statement and Form PTO-1449.

No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to the enclosed materials, the Commissioner is hereby authorized to deduct said fees from Fulbright & Jaworski Deposit Account No.: 50-1212/10109245/GNS.

Please date stamp and return the enclosed postcard evidencing receipt of these materials.

Respectfully submitted,

Gina N. Shishima Reg. No. 45,104

GNS/cas

Encl: as noted

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#### IN THE UNITED STATES PATENT AND TRADEMARK-OFFICE

In re Application of: Gang An et al.

Serial No.: 09/974,546

Filed: October 10, 2001

For: BIOMARKERS AND TARGETS FOR DIAGNOSIS, PROGNOSIS AND MANAGEMENT OF PROSTATE, BREAST AND BLADDER CANCER

Group Art Unit: Unknown

Examiner: Unknown

Atty. Dkt. No.: UROC:018USD2/GNS

CERTIFICATE OF MAILING 37 C.F.R 1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231, on the date

December 17, 2001

Date

Gina N. Shishima INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents Washington, D.C. 20231

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record.

In accordance with 37 C.F.R §§ 1.97(g), (h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

The present Information Disclosure Statement is being filed prior to the receipt of a first

Official Action reflecting an examination on the merits, and hence is believed to be timely filed

in accordance with 37 C.F.R § 1.97(b). No fees are believed to be due in connection with the

filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R.

§§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the

Commissioner is hereby authorized to deduct said fees from Fulbright & Jaworski Deposit

Account No.: 50-1212/10109245/GNS.

This application is a divisional application of Serial No. 09/097,199, filed June 12, 1998,

and is relied upon for an earlier filing date under 35 U.S.C. § 120. In accordance with Rule 37

C.F.R. § 1.98(d) copies of the listed documents are not enclosed as they have been previously

cited by or submitted to the Patent and Trademark Office in prior application Serial No.

09/097,199.

Applicants respectfully request that the listed documents be made of record in the present

case.

Respectfully submitted,

Gina N. Shishima

Reg. No. 45,104

Attorney for Applicants

FULBRIGHT & JAWORSKI L.L.P. 600 Congress Avenue, Suite 2400 Austin, Texas 78701 (512) 474-5201

Date:

December 17, 2001

Form PTO-1449 (modified)

ATTY. DOCKET NO. UROC:018USD2/GNS

Serial No. 09/974,546

O I ps of Patents and Publications for Applicant's

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PRMATION DISCLOSURE STATEMENT

David Ralph, Gang An, Mark O'Hara and Robert Veltri

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Filing Date: October 10, 2001 Group: Unknown

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Foreign Patent Documents

Other Art

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#### **U.S. Patent Documents**

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Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date if 290
	A1	5,262,311	11/16/93	Pardee et al.	435	91.2; 6	
	A2	5,633,161	05/27/97	Shyjan	435	325	
	A3	5,639,656	06/17/97	Wright, Jr.	435	344.1	
	A4	5,665,547	09/09/97	Pardee et al.	435	6	
~	A5	5,342,762	08/30/94	Mosher et al.	435	69.1	
	A6	5,455,158	10/03/95	Vogel et al.	435	7.21	
	A7	5,487,985	01/30/96	McClelland et al.	435	91.2	
	A8	5,550,214	08/27/96	Eberlain et al.	530	328	

## **Foreign Patent Documents**

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	B1	WO 94/10343	05-11-94	PCT	C12Q	1/68	

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Exam. Init.	Ref. Des.	Citation				
	C1	Alcaraz et al., "Aneuploidy and aneusomy of chromosome 7 detected by fluorescence in situ hybridization are markers of poor prognosis in prostate cancer", Cancer Res., 54:3998-4002, 1994.				
	C2	An et al., "Isolation of Genes differentially expressed in prostate cancer cells with metastatic potential by arbitrarily-primed differential analyses (ADA)," Proc. Amer. Assn. Canc. Res., 36:82(491), 1995.				
:	C3	Bookstein <i>et al.</i> , "Suppression of tumorigenicity of human prostate carcinoma cells by replacing a mutated RB gene," <i>Science</i> , 247:712-715, 1990.				

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Examiner:

**Date Considered:** 

### Form PTO-1449 (modified)

(modified) ATTY. DOCKET NO. UROC:018USD2/GNS

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List of Patents and Publications for Applicant's

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FORMATION DISCLOSURE STATEMENT

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:	C4	Bookstein et al., "Promoter deletion and loss of retinoblastoma gene expression in human prostate carcinoma," Proc. Natl. Acad. Sci. USA, 87:7762-7766, 1990.				
	C5	Bova et al., "Homozygous deletion and frequent allelic loss of chromosome 8p22 loci in human prostate cancer," Cancer Res., 53:3869-3873, 1993.				
	C6	Carter et al., "Allelic loss of chromosomes 16q and 10q in human prostate cancer," Proc. Natl. Acad. Sci. USA, 87:8751-8755, 1990.				
	C7	Chen et al., "Androgen-independent human prostate cancer progression: the isolation of nove stage-specific sequences using differential mRNA display," Proc. Natl. Urol. Assn., 153:267A, 1995.				
	C8	Donohue et al., "A delayed-early gene activated by fibroblast growth factor-1 encodes a proteir related to aldose reductase", J. Biol. Chem., 269(11):8604-8609, 1994.				
-	C9	Dumont et al., "Relationship between multiple biologic effects of rapamycin and the inhibition of pp70S6 protein kinase activity," J. Immunology, 992-1003, 1994.				
	C10	Isaacs et al., "Molecular biology of prostate cancer," Seminars in Oncology, 21(5):514-521 1994.				
	C11	Isaacs et al., "Wild-type p53 suppresses growth of human prostate cancer cells containing mutant p53 Alleles," Cancer Res., 51:4716-4720, 1991.				
	C12	Liang, Peng, Pardee, "Differential display of eukaryotic messenger RNA by means of the polymerase chain reaction", <i>Science</i> , 257:967-971, 1992.				
	C13	Liang et al., "Differential display and cloning of messenger RNAs from human breast cancer versus mammary epithelial cells", Cancer Res., 52:6966-6968, 1992.				
	C14	Macoska et al., "Fluorescence in Situ hybridization analysis of 8p allelic loss and chromosome 8 instability in human prostate cancer", Cancer Research, 54:3824-3830, 1994.				
	C15	Mok et al., "Molecular cloning of differentially expressed genes in human epithelial ovariar cancer", Gynecological Oncology, 52:247-252, 1994.				
	C16	Morton et al., "Multivariate analysis of the relationship between survival and the microstage of primary melanoma by clark level and breslow thickness," Cancer, 71(11):3737-3743, 1993.				

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Serial No. 09/974,546

List of Patents and Publications for Applicant's

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	C17	Morton et al., "Reduction of E-cadherin levels and deletion of the α-catenin gene in human prostate cancer cells," Cancer Research, 53:3585-3590, 1993.
	C18	Qiao et al., "Effects of suramin on expression of proliferation associated nuclear antigens in DU-145 prostate carcinoma cells", Biochemical and Biophysical Research Communications, 201(2):581-588, 1994.
	C19	Riber, Manuel, Rieber, "Cyclin-dependent kinase 2 and cyclin A interaction with E2F are targets for tyrosine induction of B16 melanoma terminal differentiation", Cell Growth and Differentiation, 5:1339-1346, 1994.
	C20	Sager et al., "Identification by differential display of alpha-6 integrin as a candidate tumor suppressor gene," Methodology Communications, 7:964-970, July, 1993.
	C21	Scott et al., "A truncated intracellular HER2/neu receptor produced by alternative RNA processing affects growth of human carcinoma cells," <i>Molecular and Cellular Biology</i> , 13(4):2247-2257, 1993.
	C22	Slamon et al., "Expression of cellular oncogenes in human malignancies," Science, 224:256-262, 1984.
	C23	Takahashi et al., "Potential markers of prostate cancer aggressiveness detected by fluorescence in Situ hybridization in needle biopsies," Cancer Research, 54:3574-3579, 1994.
	C24	Umbas et al., "Expression of the cellular adhesion molecule E-cadherin is reduced or absent in high-grade prostate cancer," Cancer Research, 52:5104-5109, 1992.
	C25	Visakorpi et al., "Sensitive detection of chromosome copy number abberations in prostate cancer by fluorescence In Situ hybridization," J. Pathology, 145(3):624-630, 1994.
	C26	Watson and Fleming, "Isolation of differentially expressed sequence tags from human breast cancer," Cancer Research, 54:4598-4602, 1994.
	C27	Webb and Lin, "Urinary fibronectin-potential as a biomarker in prostatic cancer," <i>Investigative Urology</i> , 17(5)401-404, 1980.
	C28	Welsh et al., "Arbitrarily primed PCR fingerprinting of RNA," Nucleic Acids Research, 20(19):4965-4970, 1992.

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**Applicants** 

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	C30	An et al., "Identification of novel gene markers in prostate disease by RNA fingerprinting," Proc. American Assoc. Cancer Res. Annual Mtg, Abstract No. 1692 37(0):248, 1996.
	C31	An et al., "Sensitive, nonradioactive differential display method using chemiluminescent detection," Biotechniques, 20(3):342, 344, 346, 1996.
	C32	Blok et al., "Isolation of cDNAs that are differentially expressed between androgen-dependent and androgen-independent prostate carcinoma cells using differential display PCR <sup>TM</sup> ", Prostate, 26(4):213-224, 1995.
	C33	Hamdy et al., "Circulating prostate specific antigen-positive cells correlate with metastatic prostate cancer, Brit. J. Urology, 69(4):392-396, 1992.
	C34	Robson et al., "Identification of prostatic androgen regulated genes using the differential display technique, Proc. American Assoc. Cancer Research Annual Meeting, Abstract No. 1589. 36:266, 1995.
	C35	EMBL. Sequence Data Library, Heidelberg, BRD, XP002019347, Accession no. W67972
	C36	PCT Search Report mailed March 7, 1997.
	C37	Adam and Wright Jr., "Identification of biomarkers in benign: prostate hyperplasia and prostate carcinoma by differential display," <i>Proceedings</i> , 86th Annual Meeting American Association for Cancer Research, March 1995.
	C38	Badalament et al., "An algorithm for predicting nonorgan confined prostate cancer using the results obtained from sextant core biopsies with prostate specific antigen level," J. Urol., 156:1375-1380, 1996.
	C39	Bussemakers et al., "Identification of high mobility group protein I(Y) as potential progression marker for prostate cancer by differential hybridization analysis," Cancer Res., 51:606-611, 1991.
	C40	Deguchi et al., "Detection of micrometastatic prostate cancer cells in lymph nodes by reverse transcriptase-polymerase chain reaction," Cancer Research, 53:5350-5354, 1993.

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List of Patents and Publications for Applicant's

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David Ralph, Gang An, Mark O'Hara and Robert Veltri

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October 10, 2001

Group: Unknown

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	C41	Garcia-Arenas et al., "The expression of prostatic acid phosphatase in transcriptionally regulated in human prostate carcinoma cells," Mol. Cell. Endocrin., 111:29-37, 1995.
	C42	Kawasaki and Wang, "Detection of gene expression," In: PCR Technology, Henry A. Erlich (ed.), Stockton Press, 1989.
	C43	O'Dowd et al., "Update on the appropriate staging evaluation for newly diagnosed prostate cancer," J. Urol., 158:687-698, 1997.
	C44	Orozco et al., "Observations on pathology trends in 62,537 prostate biopsies obtained from urology private practices in the United States," <i>Urology</i> , 51(2):186-195, 1998.
,	C45	Prashar et al., "Analysis of differential gene expression by display of 3' end restriction fragments of cDNAs," Proc. Natl. Acad. Sci. USA, 93:569-663, 1996.
	C46	Veltri et al., "Ability to predict biochemical progression using gleason score and a computer-generated quantitative nuclear grade derived from cancer cell nuclei," <i>Urology</i> , 48(5):685-691, 1996.
	C47	Wingo et al., "An adjustment to the 1997 estimate for new prostate cancer cases," CA-A Cancer Journal for Clinicians, 47(4):239-242, 1997.
	C48	An et al., "Differential expression of full-length and a truncated Her-2/neu oncogene receptor in prostate cancer assessed using relative quantitative RT-PCR," Molecular Urology, 2(4):305-310, 1998.
	C49	Veltri et al., "Interleukin-8 serum levels in patients with benign prostatic hyperplasia and prostate cancer," <i>Urology</i> , 53(1):139-147, 1999.
	C50	Veltri et al., "The role of biopsy pathology, quantitative nuclear morphometry, and biomarkers in the preoperative prediction of prostate cancer staging and prognosis," Seminars in Urologic Oncology, 16(3):106-117, 1998.
	C51	Chen et al., "Androgen-independent human prostate cancer progression: the isolation of novel stage-specific sequences using differential mRNA display," J. Urol., 153(Supp. 4):267, Abstract 154, April 1995.
	C52	Adam et al. "Identification of biomarkers in benign prostate hyperplasia and prostate carcinoma by differential display," Proc. Amer. Assoc. Cancer Res., 36:25, Abstract 150, March 1995.

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